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QUESTÃO DE RESPEITO

*Instructions Manual*

# SONOPULSE
## Compact 1 MHz

**Therapeutic Ultrasound 1 MHz**

**Manufactured by Ibramed**
**Indústria Brasileira de Equipamentos Médicos EIREILI.**
**Made in Brazil**
**ANVISA Nº 10360310025**
**4th edition (REV_07/2012)**

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# SYMBOL DEFINITIONS

**BELOW ARE THE DEFINITIONS OF THE SYMBOLS USED ON THE EQUIPMENT AND THROUGHOUT THE INSTRUCTIONS FOUND IN THIS MANUAL. UNDERSTAND THESE SYMBOLS AND THEIR DEFINITIONS BEFORE OPERATING THIS EQUIPMENT**

Caution! Refer to user manual.

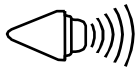
CLASS II Electrical equipment.

IPX1 Protected against dripping water.

IPX7 Protected against the effects of immersion.

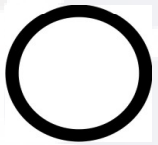
TYPE BF Electrical Equipment.

Dangerous Voltage.



Transducer.

COMBINE THERAPY IN Combined therapy IN.



Off Switch.

On Switch.

Start treatment.

Stop treatment.

V~ Alternating Current.

# SYMBOLS DEFINITIONS

## CARTON

Fragile.

This side up.

Limits of temperature for storage and packaging in °C (Celsius Degrees).

Keep away from the rain.

Stacking up.

Do not use if the packaging is damaged.

Refer to operating instructions for correct product use.

Manufacturer’s name and address.

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## ABREVIATIONS GLOSSARY

| | |
|---|---|
| **MHz** | Megahertz (million pulses ($10^6$) by second) |
| **ERA** | Effective Radiating Area |
| **W** | Watt (s) |
| **W/cm²** | Watt (s) per square centimeter |
| **cm²** | Square centimeter |
| **VA** | Volt Ampere |
| **BNR** | Beam Non-Uniformity Ratio |
| **Min** | Minute |

## FIGURES GLOSSARY


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This user manual allows the user to efficiently use the **SONOPULSE Compact 1 MHz**. It also gives suggestions for treatment protocols so that you can use your equipment to its full potential.

Consult other resources for additional information regarding the uses of ultrasound before attempting any treatment on a patient. Users must read, understand and follow the information in this manual for each mode of treatment available, as well as the indications, contra indications, warnings and precautions.

The specifications and instructions in this manual are in effect at the time of its publication. These instructions may be updated at any time at the manufacturer's discretion. Visit our web site for updates.



## ESSENTIAL PERFORMANCE

**SONOPULSE Compact 1 MHz** is a therapeutic ultrasound micro controlled device in the frequencies of 1 MHz, designed to be used for aesthetic and physiotherapy treatments. **SONOPULSE Compact 1 MHz** allows the choice of ERA (Effective Radiating Area) of 7 $cm^2$, 1 MHz frequency with the ERA 7 $cm^2$. The average ultrasound output power is 21 Watts for the ERA of 7 $cm^2$, therefore, the maximum intensity is 3 $W/cm^2$. The ultrasound emission mode can be adjusted to continuous or pulsed. The pulsed mode has pulse repetition frequencies of 100 Hz, 48 Hz or 16 Hz, with pulse ratio of ½ (50%) 1/5 (20%) or 1/10 (10%). **SONOPULSE Compact 1 MHz** also has a **PROG** key, which allows the choice of pre programmed treatment programs (recorded on the memory of the device).

**SONOPULSE Compact 1 MHz** must be used with complaint gel. The wavelength of 1 MHz penetrates to a depth of approximately 5 cm.

This device must be used only under prescription and supervision of a licensed professional.

## PRECAUTIONARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment prior to therapy session.

Text with a "CAUTION" indicator refers to potential safety infractions that could cause minor to moderate injury or damage to equipment.

Text with a "WARNING" indicator refers to potential safety infractions that could cause serious injury and equipment damage.

Text with a "DANGER" indicator refers to potential safety infractions that represent immediately life threatening situations that would result in death or serious injury.

- Read, comprehend and practice the precaution and operation instructions. Know the limitations and dangers associated with the use of any electrical stimulation. Observe the precaution and operation labels placed on this unit.
- Do not operate this unit in an environment where other devices intentionally radiate electromagnetic energy in an unprotected manner.
- Check the cables and connectors before each use.
- The **SONOPULSE Compact 1 MHz** stimulator is not designed to prevent the penetration of water and other liquids. Penetration of water and other liquids may cause malfunction of the internal components of the system, and consequently, promote risk of injure to the patient.
- Disconnect the plug from the power outlet when the device is not used for long periods of time.
- The applicator should be operated only by the handle to avoid exposure to unwanted emission of ultrasound.

## WARNING

- In order to be protected from the risk of fire, use only spare fuses of the same type and class.
- Make sure the unit is grounded, connecting it to a grounded power outlet in conformity with the applicable local and national electrical codes.
- Before treating the patient, it is necessary to know the operational procedures for each treatment mode available, as well as the indications, contra indications, warnings and precautions. Refer to other sources to obtain additional information on electrotherapy applications.
- To avoid electrical shock, turn the device off the power supply line before any maintenance procedure.
- The ultrasound treatment must not be applied on swollen infected or inflamed areas, or on skin eruptions such as phlebitis, thrombophlebitis, varicose veins, etc.
- Ultrasound treatment must not be applied on or next to cancerous lesions.

## DANGER

- Patients with neurostimulation devices or implanted pacemakers must be distant from any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy, or laser diathermy and must not be treated with these on any part of their bodies. The diathermy energy (shortwave, microwave, ultrasound and laser) may be transferred through the implanted neurostimulation system, and it may cause damage to the tissues, and result in serious injury or death. Damage, injury and death may occur during diathermy therapy even if the implanted system is turned off.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide. Equipment is not the AP or APG category.

## INDICATIONS

Therapeutic ultrasound is commonly indicated for:

- Pain relief
- Reduction of muscle spasm
- Localized increase in blood flow
- Increase in range of motion in contracted joints using heat associated with stretch techniques..

Relief of pain, muscle spasms and contracted joints may be associated with:

- Adhesive capsulitis.
- Bursitis with mild calcification.
- Myositis.
- Lesion of soft tissues.
- Post lesion shortening of tendons and scar.

Relief of chronic pain and muscle contracture may result from:

- Capsular tension.
- Capsular scar.

## PRECAUTIONS

- Ultrasound treatment must be avoided over the stellate ganglion, spinal cord after laminectomy, when great tissue resections have been performed, under subcutaneous major nerves and the cranium.
- Ultrasound must not be applied in areas of reduced sensation or circulation or over anesthetic areas. Patients with reduced sensation are not capable of warning the professional in case there is discomfort and in patients with compromised circulation there may be an excessive buildup of heat in the treated area.
- Patients with hemorrhagic diastheses or hemorrhagic disorders must be treated with care.
- Professionals operating the device on a daily basis must not be exposed to therapeutic ultrasound. The applicators handles have been developed to allow the professional to protect the hands from ultrasound when performing underwater treatment.
- If a patient complains of deep periosteal pain during ultrasound treatment, the intensity should be reduced to a comfortable level.
- Heating must be avoided during the acute or sub-acute phase of arthritis.
- Other treatments with electronic devices or hydro massage devices which may come into contact with the patient during ultrasound therapeutic treatment must be appropriately tested to assure the safety of the operation.
- The operator should manipulate the applicator only by handle during the application.

## CONTRA INDICATIONS

- Therapeutic ultrasound must not be applied over the pregnant uterus or potentially pregnant uterus.
- Therapeutic ultrasound must not be applied for undiagnosed pain.
- Therapeutic ultrasound must not be applied over neoplastic areas or over areas from which tumors have been removed.
- Therapeutic ultrasound must not be applied over the eyes.
- Therapeutic ultrasound must not be applied on ischemic tissues, where the blood supply may be incapable of following the increase in metabolic demand and result in necrosis.
- Therapeutic ultrasound must not be applied over bone growth centers.
- Ultrasound therapy is not recommended for patients with implanted electronic devices (cardiac pacemakers, deep brain stimulation devices).
- Do not apply ultrasound over areas previously treated with radiotherapy.
- Ultrasound must not be applied over the testes, to avoid increases in temperatures.
- Ultrasound must not be applied over the heart.
- Therapeutic ultrasound must not be applied over areas of thrombophlebitis deep vein thrombosis emboli and severe atherosclerosis.
- Therapeutic ultrasound must not be applied in case of suspected serious infectious disease and in diseases in which, for general medical purposes, it is advisable to suppress heat and fever.

## ADVERSE REACTIONS

- Therapeutic ultrasound, when applied in continuous circular movements, may cause a sensation of numbness and/or heat. If, however, the applicator is kept over the same place for more than a few seconds in high energies, it may become uncomfortable.

## PATIENT POPULATION

• Patients over 12 years old, under this age only by medical prescription or physiotherapeutic indication;
• Patients over 35 kg, under this weight only by medical prescription or physiotherapeutic indication;
• There are no restrictions as of nationality;
• Patients with preserved level of conscience and sensitivity.

## CONDITIONS OF USE

• There are no requisites about a maximum level of education for the intended use.
• Regarding the minimum level of knowledge of the user, it is necessary that the user knows the electro physical agents and their therapeutical effects. The user must know physiology, anatomy, and the basic sciences: chemistry, physics, and biology. The user is supposed to have studied or be presently studying physiology and anatomy;
• A maximum level of knowledge is not required from the user;
• The instructions of use are available in Portuguese, Spanish and English;
• Regarding the minimum level of experience of the user, it is necessary that the instructions of use are read carefully and all the instructions are understood before the use of the device;
• There are no admissible deficiencies for the use of the equipment;
• Regarding the frequency of use, this device is used according to clinical needs, up to several times a day and is reusable;
• Regarding mobility, this device is considered a portable device.

# RESPONSIBILITY FOR USE ELECTROMEDICAL EQUIPMENT

The use of electromedical equipment is restricted to a physician or under his command, the physical therapists or health professionals properly licensed. The professional will be responsible for properly licensed use and operation of the equipment. IBRAMED makes no representations regarding laws and federal, state or local laws that may apply to the use and operation of any electromedical equipment.

The physician or under his command, also the physical therapist or other professional health care licensed assumes total and full commitment to contact the local certifying agencies to determine any credential required by law for clinical use and operation of this equipment.

The use of electromedical equipment must comply with the local, state and federal country.

## SHIPPING DAMAGE

Your **SONOPULSE Compact 1 MHz** is shipped complete in one carton. Upon receipt, inspect carton and unit for visible and hidden damage. In case of damage, keep all shipping materials including carton and contact the shipping agent responsible for the delivery of the unit. All claims relating to damage during transport should be filed directly with them. The manufacturer will not be liable for any damage during shipping, nor allow for adjustments unless proper formal claim has been filed by the receiver against the carrier. The carton in which your **SONOPULSE Compact 1 MHz** was received is specially designed to protect the unit during shipping. Please keep all shipping materials in case you need to return your unit for servicing.

## INSTALLATION, CARE AND CLEANING

### Installation Instructions

**1.** Connect the line cord to the back of the **SONOPULSE Compact 1 MHz.**

**2.** Plug the line cord into a grounded wall outlet (100-240V ~ 50/60 Hz).

**3.** Plug the ultrasound cables into the correct connections.

**4.** Switch on your equipment.

### SONOPULSE Compact 1 MHz Care Instructions

- Avoid areas subject to vibrations.
- Install the equipment on a firm and level surface, in open air.
- Do not block ventilation.
- Avoid humid, hot and dusty environments.
- Make sure the area around the network cable is free.
- Do not insert objects into device holes.

**CAUTION**

**Proper installation, operation and maintenance of the equipment prevents security risks.**

### Cleaning the SONOPULSE Compact 1 MHz

- Disconnect the system from the power source, wipe with a clean, lint free cloth moistened with water and mild antibacterial soap.
- If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.
- Do not place the system in liquids.

### ENVIRONMENTAL PROTECTION

The **SONOPULSE Compact 1 MHz** is an electronic device and has heavy metals such as lead. Thus, there are risks of contamination to the environment associated with the disposal of this equipment and its accessories at the end of their useful lives. The **SONOPULSE Compact 1 MHz**, parts and accessories must be disposed of as waste. Contact your local distributor for information on rules and laws regarding the disposal of waste electrical, electronic equipment and accessories.

**CAUTION**

**THE DEVICE AND ITS CONSUMABLE PARTS MUST BE DISPOSED OF, AT END OF LIFE, ACCORDING TO THE APPLICABLE FEDERAL AND/OR STATE AND /OR LOCAL REGULATIONS.**

## ELECTRICAL FEED

**SONOPULSE Compact 1 MHz** is a protective CLASS II device with applied part type BF of safety and protection. **SONOPULSE Compact 1 MHz** works in power supply tension in the range of 100 - 240V ~ 50/60 Hz. Just connect the device to the power line and it will perform the selection of power tension automatically. The connector cable to the power supply line is detachable. The device uses the power line plug as a resource to electrically separate its circuits in relation to the power supply line in all poles.

## NOTES

In the rear part of **SONOPULSE Compact 1 MHz** there is a protection fuse. To replace it, **turn the device off the power supply line** and with the help of a screwdriver, remove the protection lid, disconnect the fuse, perform the replacement and reinsert the lid.

Always use the fuses indicated by IBRAMED. Use a fuse for nominal current of 5.0A, operation tension of 250V~ and snap action model 20AG (50A rupture current).

**SONOPULSE Compact 1 MHz** does not need any type of power stabilizer.  Never use a power stabilizer.

Before turning on **SONOPULSE Compact 1 MHz** make sure:

- The tension and frequency of the local power supply line of the establishment where the device is installed are equal to the one described on the label describing characteristics of tension and power located at the rear part of the device.
- To prevent electrical shock, do not use the plug in the device with extension cables, or any other types of sockets except the terminals connect perfectly in the receptacle.
- Cleansing and disinfection must always be performed with the power plug off of the power supply line.
- Maintenance and technical assistance of **SONOPULSE Compact 1 MHz** must always be performed at unauthorized service, only by qualified technicians.

**CAUTION**

**Inside the device there are dangerous tensions.**
**Never open the device.**

# CAUTION

- This unit is not designed to be used where there is explosion hazard, such as anesthesia departments or in the presence of an anesthetic flammable when mixed with air, oxygen or nitrous oxide.

- Using cables, electrodes and other accessories from other manufacturers and/or different from those specified in this manual as well as the replacement of internal components **SONOPULSE Compact 1 MHz** may result in increased emissions or decreased immunity of the equipment.

- **SONOPULSE Compact 1 MHz** equipment is intended for use only by health care professionals. The **SONOPULSE Compact 1 MHz** may cause radio interference or disrupt equipment operations nearby. It may be necessary to adopt mitigation procedures, such as reorienting or relocating the equipment or shielding of the site.

- Portable and Mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Devices.

## POTENTIAL ELECTROMAGNETIC INTERFERENCE

As for the limits of electromagnetic interference, **SONOPULSE Compact 1 MHz** is an electromagnetic device of Group 1 Class A. The simultaneous connection from the patient to **SONOPULSE Compact 1 MHz** and to high frequency surgical equipment may result in burns in the ultrasonic transducer application area and possible damage to the device. Short distance operation (1 meter, for example) of short wave or microwave therapy equipment may produce instability in the output of the device. To prevent electromagnetic interference, we suggest that one group of power supply line is used for **SONOPULSE Compact 1 MHz** and another separate group is used for short wave or microwave equipment. We also suggest that the patient, **SONOPULSE Compact 1 MHz** e and connection cables are installed at least 3 meters away from short wave and microwave therapy equipment.

Medical Electrical Devices requires special attention regarding Electromagnetic Compatibility (EMC) and must be installed and put into service according to the EMC information provided in the following tables.

<table>
<tr><th colspan="3">Manufacturer’s guidelines and declaration – Electromagnetic emissions</th></tr>
<tr><td colspan="3">SONOPULSE Compact 1 MHz is destined to be used in the electromagnetic environment specified below. The user of the equipment should be sure that it will be used in this environment.</td></tr>
<tr><th>Emission test</th><th>Conformity</th><th>Electromagnetic emissions</th></tr>
<tr><td>RF Emissions<br>NBR IEC CISPR 11<br>IEC CISPR 11</td><td>Group 1</td><td rowspan="4">SONOPULSE Compact 1 MHz emits RF energy only for its internal functions. However, its RF emissions are very low and it is unlikely to cause any interference in nearby electronic equipment.<br><br>SONOPULSE Compact 1 MHz is suitable to be used in all kinds of places other than residential and which are not directly connected to the public distribution of low voltage which supplies the domestic buildings.</td></tr>
<tr><td>RF Emissions<br>NBR IEC CISPR 11<br>IEC CISPR 11</td><td>Class A</td></tr>
<tr><td>Harmonic Emissions<br>IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Emissions due to the fluctuation/ scintillation<br><br>IEC 61000-3-3</td><td>Class A</td></tr>
</table>

| **Manufacturer's guidelines and declaration – Electromagnetic immunity** | | | |
|---|---|---|---|
| **SONOPULSE Compact 1 MHz** is destined to be used in the electromagnetic environment specified below. The user of the equipment should ensure that it is used in such environment. | | | |
| **Immunity Test** | **Test level IEC 60601** | **Conformity level** | **Electromagnetic environment – orientations** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV by contact<br>± 8 kV by air | ± 6 kV by contact<br>± 8 kV by air | The floor should be wooden, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Fast electric transitories / pulse train (Burst) IEC 61000-4-4 | ± 2 kV in the feeding lines<br>± 1 kV in the input/output lines | ± 2 kV in the feeding lines<br>± 1 kV in the input/output lines | The quality of power supply should be that of a hospital environment a or typical commercial building. |
| Outbreaks IEC 61000-4-5 | ± 1 kV diferencial mode<br>± 2 kV common mode | ± 1 kV diferencial mode<br>± 2 kV common mode | The quality of power supply should be that of a typical commercial or hospital environment. |

| **Immunity test** | **Test level IEC 60601** | **Conformity level** | **Electromagnetic environment -orientations** |
|---|---|---|---|
| Voltage drops, short interruptions and voltage variations in power input lines<br><br>IEC 61000-4-11 | < 5% U<br>(> 95% voltage drops in U ) by 0,5 cycle<br><br>40% U<br>(60% of voltage drops in U )by 5 cycles<br><br>70% U<br>(30% of voltage drops in U ) by 25 cycles<br><br>< 5% U<br>(> 95% of voltage drops in U ) by 5 seconds | < 5% U<br>(> 95 % voltage drops in U ) by 0,5 cycle<br><br>40% U<br>(60% of voltage drops in U ) by 5 cycles<br><br>70% U<br>(30% of voltage drops in U ) by 25 cycles<br><br>< 5% U<br>(> 95% of voltage drops in U ) by 5 seconds | The quality of power supply should be that of a typical commercial or hospital environment. If the user's equipment requires continued operation during power failure, it is recommended the equipment be powered by an uninterruptedly power supply or battery. |
| Magnetic field at power frequency (50/60 Hz)<br><br>IEC 61000-4-8 | 3 A/m | 3 A/m | Magnetic fields at power frequency should be at the level of a typical location in a typical commercial or hospital environment. |
| NOTE: $U_T$ is the C.A. voltage before applying the test | | | |

| **Manufacturer's guidelines and declaration – Electromagnetic immunity** | | | |
|---|---|---|---|
| **SONOPULSE Compact 1 MHz** is destined to be used in the electromagnetic environment specified below. The user of the equipment should ensure that it is used in such environment. | | | |
| **Immunity test** | **Test level IEC 60601** | **Conformity level** | **Electromagnetic environment – guidelines** |
| RF Conducted<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 V | Communication equipment of RF portable and mobile should not be used near any part of **SONOPULSE Compact 1 MHz** including cable with separation distances smaller than the recommended, calculated from the equation applicable to the transmitter frequency.<br>Recommended separation distance:<br>$d = 1.2 \sqrt{P}$<br>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.4 \sqrt{P}$ 800 MHz to 2.5 GHz<br><br>Where P is the maximum nominal output power in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). It is recommended that the field intensity established by the RF transmitter, as determined by an electromagnetic inspection on the local, be smaller than the conformity level in each frequency range . Interference may occur around the equipment marked with this symbol: |
| RF Radiated<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | |

NOTE 1: At 80 MHz and 800 MHz it is applied to the higher frequency range.
NOTE 2: These guidelines may not be applicable to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths set by fixed transmitters, such as radio base stations, telephone (cellular / cordless) telephones and land mobile radios, amateur radio, AM / FM radio and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it is recommended an electromagnetic inspection on the place. If the measure of field strength at the location **SONOPULSE Compact 1 MHz** is used exceeds the conformity level used above, the unit must be observed to see whether the operation is normal. If an abnormal performance is observed, additional procedures may be needed, such as reorientation or replacement of the equipment. Over the frequency range from 150 KHz to 80 MHz, the field strength must be less than 10 V / m. [b]

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**Recommended separation distances between the communication equipment of RF portable and mobile and SONOPULSE Compact 1 MHz**

**SONOPULSE Compact 1 MHz** is intended to be used in an electromagnetic environment in which RF disturbances are controlled. The user of the electrostimulator can help to prevent the electromagnetic interference by maintaining the minimum distance between the portable communication equipment and mobile RF (transmitters) and, **SONOPULSE Compact 1 MHz** as recommended below, according to the maximum power of communication equipment.

| Maximum rated power output of the transmitter maximum nominal potency of transmitter output **W** | **Separation distance according to frequency of transmitter m** | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.4 \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters with a maximum nominal output power not listed above, the recommended separation distance in meters (m) can be determined by using the equation applicable to the frequency of the transmitter, where P is the maximum rated output in watts (W) According to the transmitter manufacturer.

NOTE 1: 80 MHz to 800 MHz, applies to the distance of separation for the higher frequency range.

NOTE 2 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**Equipment:**
**Serial number:**
**ANVISA Registration (M.S.):**

**Manufacturing date:**

**Expiration date: 5 years**

**Senior engineeer: Maicon Stringhetta**

**CREA - 5062850975**

## SYSTEM SPECIFICATIONS

### Dimensions

| | |
|---|---|
| **Width** | 10.6 in (27 cm) |
| **Depth** | 10.4 in (16.6 cm) |
| **Height** | 4.9 in (12.5 cm) |
| **Standard Weight** (with transducer) | 1.4 kg |

### Power

| | |
|---|---|
| Input | 100 - 240~ 50/60 Hz |
| Input power | 100 VA |
| Fuses | 5A 250~ (20AG) Fast Action |
| Electrical Class | CLASS II |
| Electrical Protection | TYPE BF |

**Range of temperature during transportation and storage:**

5 - 50°C/ 41- 122°F.

**Range of operational environment temperature:**

5 - 45 °C/ 41- 113 °F.

### Conformity Regulations

IEC 60601-1

IEC 60601-1-2

IEC 60601-2-5

IEC 60601-1-4

## SPECIFICATIONS OF ULTRASOUND

| | |
|---|---|
| Frequency | 1.1 MHz, ± 10% |
| Effective radiating area (ERA) | 7 $cm^2$; |
| Mode | Continuous |
| | Pulsed |
| Work Cycle | 20%; 50% |
| Frequency of pulse repetition | 100 Hz; 16 Hz; 48 Hz |
| Transducer of 7 $cm^2$ | 1.1 MHz ±10% |
| Treatment time | 1-30 min |
| **Output Power** | |
| Crystal of 7 $cm^2$ | 0.1 a 3.0 W/$cm^2$; 1.1 MHz |
| Maximum Amplitude (7 $cm^2$) | 21 W ± 20% |
| BNR | |
| Crystal of 7 $cm^2$ | 3 |

Note: The equipment in pulsed mode shows values of peak power, average values are equivalent to pulsed selected percentage, ex:

**Selected:**
Potency: 21 W
Duty cycle: 50%

**Average Power:** 21 x 0,5 = 10,5 W

## CONTROLS, INDICATORS AND CONNECTORS

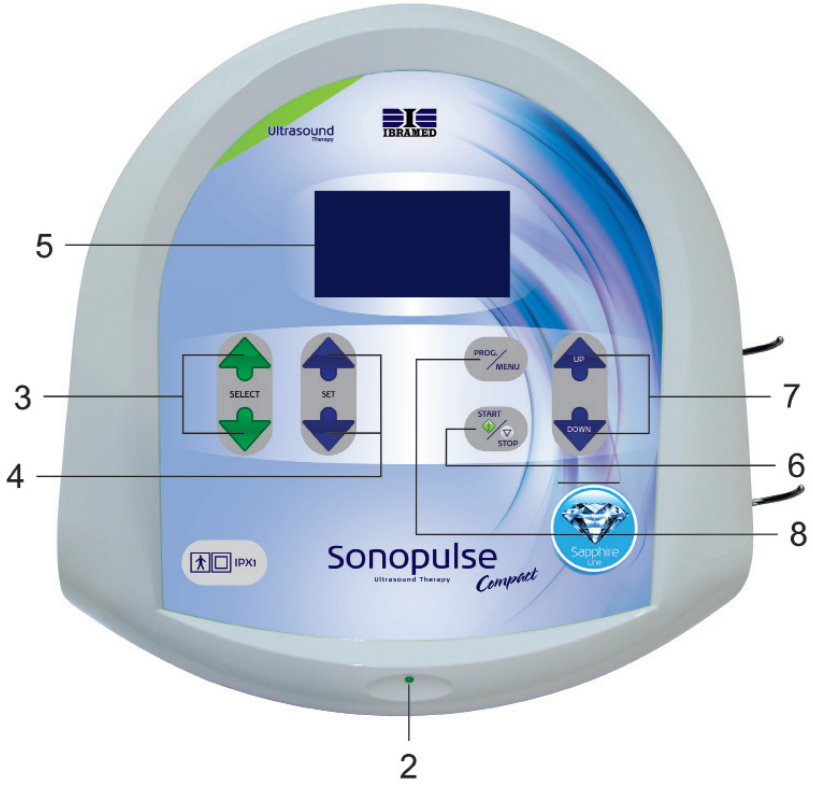



**Figure 1.** Upper view.

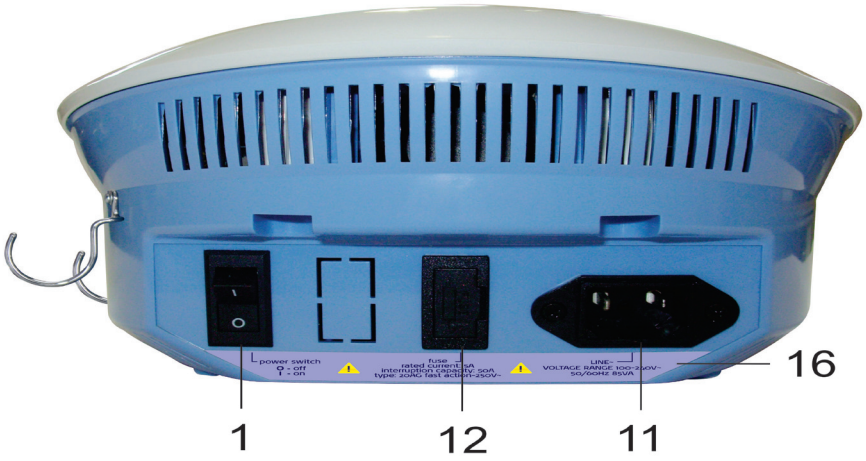



**Figure 2.** Rear view**.**

## CONTROLS, INDICATORS AND CONNECTORS

**Figure 3.** Frontal view.

**Figure 4.** Lower view.

## CONTROLS, INDICATORS AND CONNECTORS

**1- ON/OFF** switch.

**2-** Light Indicator of **ON** condition.

**3- SELECT** control keys for selecting parameters.

**4- SET** control keys – increasing or decreasing parameter values.

**5-** Alphanumerical liquid crystal display.

**6- START/STOP** control keys to start or stop treatment.

**7-UP** and **DOWN** control keys – increase or decrease ultrasound intensity.

**8-** Control keys **PROG/MENU**. **PROG:** Selection of preprogrammed protocols; **MENU:** Selection of language.

**9-** Connection for combined therapy with other IBRAMED equipment.

**10-** Output Connection of transducer to ultrasound.

**11-** Connection of power cable.

**12-** General technical information.

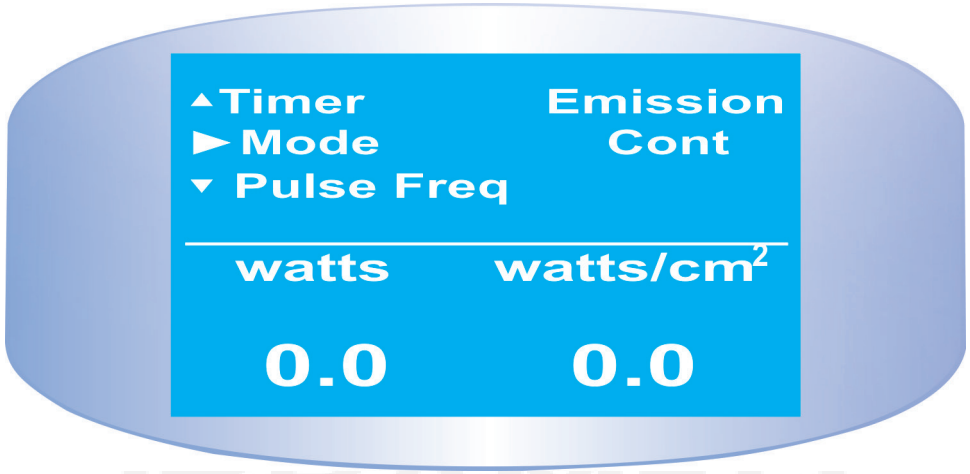
**13-** Protection fuse.

**14-** Label with technical characteristics and serial number.

**15-** Federal Law warning (only for the USA).

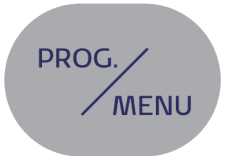
**16-** General technical information

**Read and understand these symbols and their definitions before operating the equipment**




IBRAMED

Switch used to start or stop treatment. Always press the center of the switch.




Switch with double function: **PROG** – Selection of pre programmed protocols and private protocols; **MENU** – Selection of language (Portuguese, English or Spanish).

## Read and understand these symbols and their definitions before operating the equipment

**SELECT**: switch for the selection of ultrasound parameters.

**SET**: switch: selection of values of parameters.

**UP** and **DOWN**: switch: increase or decrease of intensity: 0.1 to 3.0 W/cm$^2$.

**1 MHz ULTRASOUND:** Ultrasound transducer with ERA of 7 $cm^2$, with neutral conductor gel. (Figure 5).

**A** **B**

**CAUTION**

The screws of the transducer connector must be firmly fixed to the device.

**Figure 5. A**, Ultrasound transducer with ERA of 7 $cm^2$;
**B**, neutral conductor gel.

## PREPARING THE EQUIPMENT

Check if the power cable is connected to the power supply on the wall. Press the **ON/OFF** switch to the **ON** position. The display will show for a few seconds the presentation message which includes the model of the device and the programming software followed by the standard **SONOPULSE Compact 1 MHz** screen (Figure 6).

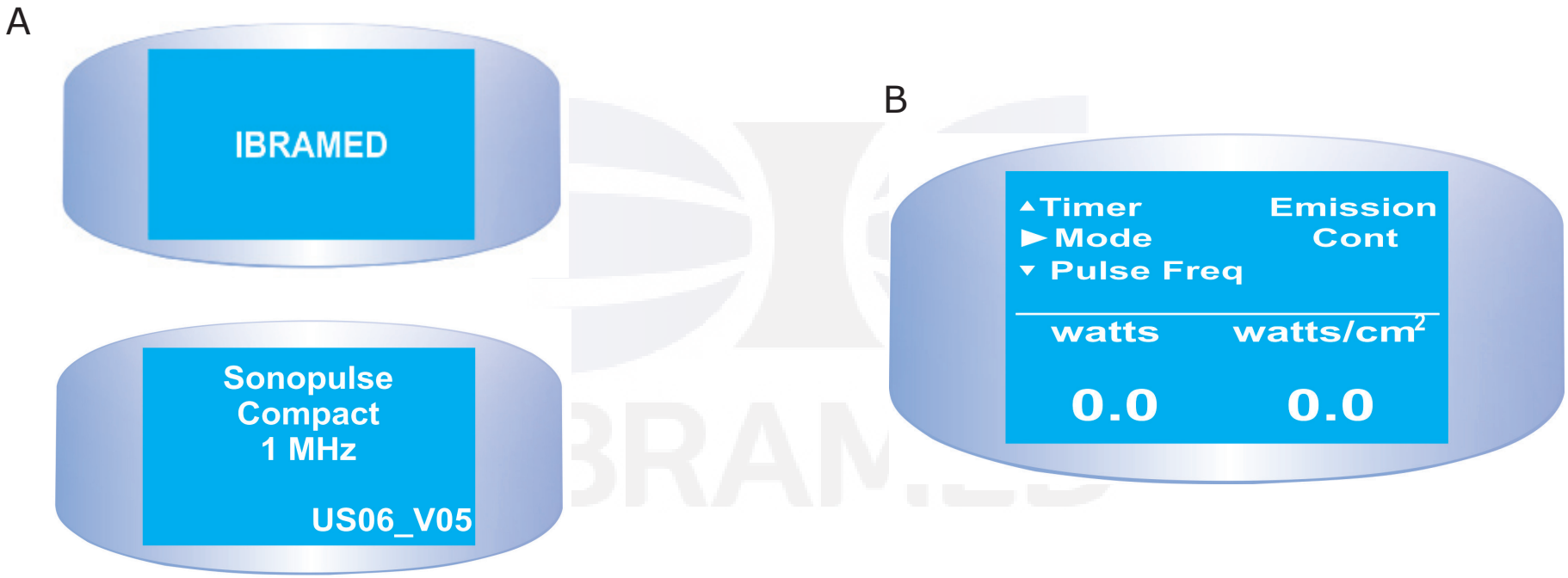



**Figure 6. A**, presentation message; **B**, standard/default **SONOPULSE Compact 1 MHz** screen.

Note that as the standard/default screen is shown, an arrow indicates the **Mode**. This arrow indicates the parameter to be programmed.

## PREPARING THE EQUIPMENT

### Selection of parameters

The **SELECT** switch allows you to select the parameters necessary for the treatment. Press **SELECT** switch up or down to move the indicating arrow to the next parameter or return to the previous parameter.

The **SET** switch allows the selection of values of each para meter necessary for treatment. Press the **SET** switch up or down to select the values

**Initiating Treatment**
Press the **START** switch to initiate treatment.

**Stopping Treatment**
Press the **STOP** switch to finalize therapy.

### Programming treatment time

Program the desired session time. At the end of the programmed time, you will hear a sound beep indicating that the treatment session has been finalized. Press the **STOP** switch, so that the sound beep is discontinued. The equipment will return to the programming status.

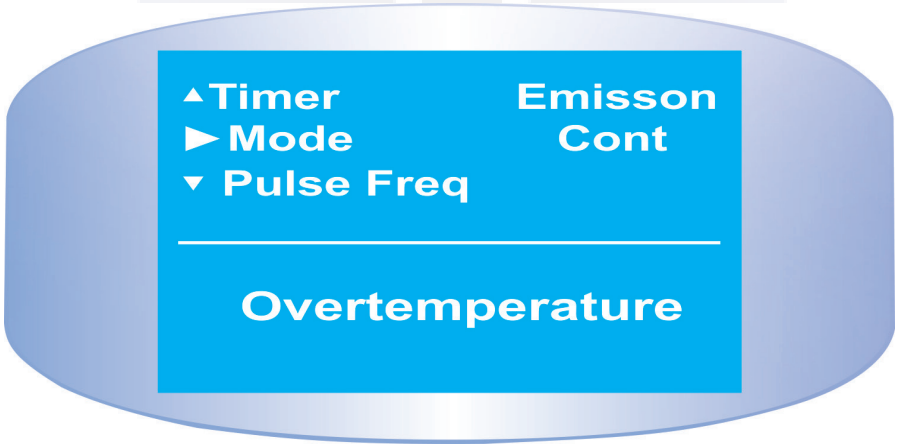
### Intensity of ultrasound

The intensity of ultrasound may be increased or decreased at any time during the session. After pressing the **START** key press the **UP** or **DOWN** switch up or down, respectively.

## TRANSDUCER PROTECTION MESSAGES

### TEMPERATURE SENSOR

Inside the **SONOPULSE Compact 1 MHz** transducer there is a temperature sensor which verifies and maintains the work temperature of the piezoelectric crystal, and consequently, the aluminum face of the transducer, which avoids the disagreeable sensation of excessive heat to the patient. This sensor is programmed so that the temperature in the aluminum never exceeds 41°C. During treatment, particularly when the couplant gel used is not of superior quality, the temperature may rise above 41°C. When that happens, the equipment will 'freeze' the programmed time and turn off the emission of ultrasound. At that moment, a sound beep will be emitted and the display will show:

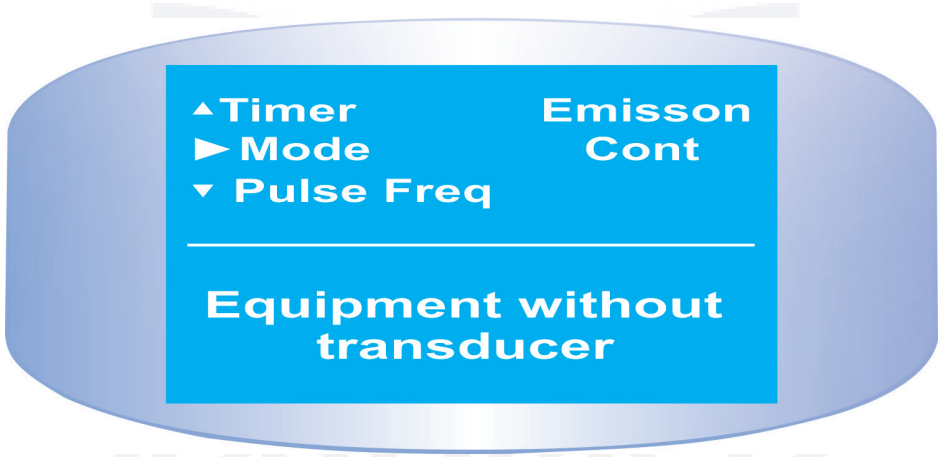



The professional should continue to 'move' the transducer, because after a few seconds the temperature will return to normal. The equipment will automatically revert the 'frozen' time, resuming the original program.

## TRANSDUCER PROTECTION MESSAGES

### EQUIPMENT WITHOUT TRANSDUCER

If the equipment is without its transducer, as the intensity of ultrasound is increased, a protection circuit will be activated and the display will show:

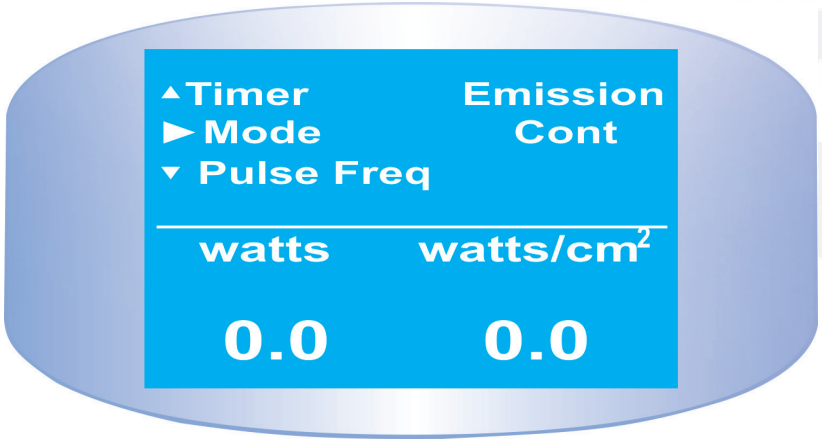



Just connect the transducer so that the message disappears and the equipment will return to its original program.

**Example**: Suppose the clinical practice or literature suggest for a particular pathology, the following parameters:

Mode: Pulsed
Pulse Freq.: 100 Hz
Duty Cycle: 50%
Time: 10 minutes
Ultrasound energy: 1 Watt/ $cm^2$

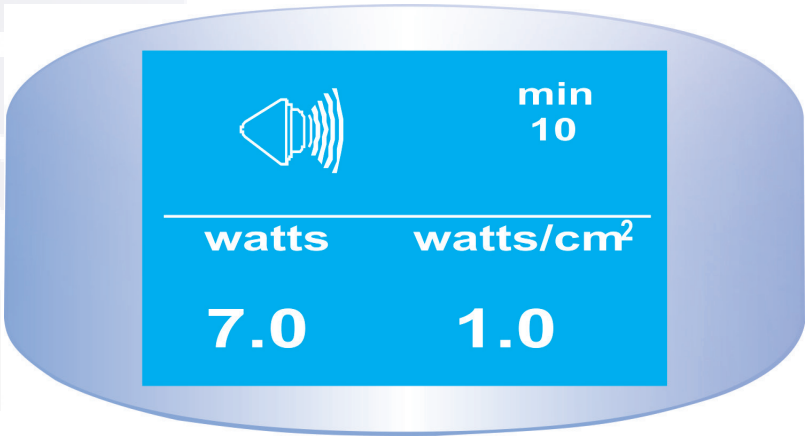
1. Turn on the equipment to initiate the standard program described above. Note the cursor on the **Mode** field.




**2.** Using the **SELECT** and **SET** switches, go through the parameters and select the values shown in the example.

**3**. Press the **UP** or **DOWN** keys to select the ultrasound intensity necessary for treatment.

**4**. Now press the **START** key to initiate the treatment. After press the **START** key, the transducer figure will appear on the display. It indicates that the ultrasound energy is activated. Now, the patient is receiving the ultrasound energy and the display will show:




**5**. At the end of the programmed time, the emission of ultrasound is interrupted and a sound beep will be emitted at the end of the treatment.

**6**. Press the **STOP** key to stop the sound beep. The equipment can now be turned off, the same program can be performed or a new program may be programmed.

## PATIENT PREPARATION

- Examine the skin for any wounds and clean the treatment area, rubbing the skin with medical use alcohol.
- Before applying the ultrasound, clean the area with and soap and water to remove the oil and possible skin fragments, thus reducing the difficulty of passage of the ultrasound through the skin.
- Clean the applicator with soap and water before each therapy session.
- Apply conductor gel over the patient's treatment area.
- Move the ultrasound transducer constantly during the session in circular moves. Examine the skin again after treatment.
- **BIOCOMPATIBILITY** of the materials in contact with the patient (ISO 10993-1): A IBRAMED states that the ultrasound transducer and coupling gel provided with the equipment do not provoke allergic reactions. The transducer and gel must be only be placed in contact with intact surface of the skin, respecting duration limit time of this contact of 24 hours. There is no risk of harmful effects to the cells, nor is there any allergic reaction or of sensitivity. The gel and the transducer The gel and the transducer (material that it is made from) do not provoke potential irritation on the skin.

Position of the ultrasound transducer for the application with ERA of 7 $cm^2$ (figure 7).

**Figure 7**. Application technique with ERA of 7 $cm^2$.

The simultaneous therapeutic application of ultrasound and functional electrostimulation may be performed with **SONOPULSE Compact 1 MHz** using an electro stimulator from the **NEURODYN** line of Ibramed equipment.

In this technique, the applicator releases ultrasonic energy and becomes an active electrode of the electrostimulation.

Follow the instructions below to perform combined therapy.

## INSTRUCTIONS FOR COMBINED THERAPY

Combined therapy may be performed by any electrostimulator of the **NEURODYN** line of Ibramed equipment connected to **SONOPULSE Compact 1 MHz** by a special connection cable (black) inserted in the combined therapy slot in the frontal part of **SONOPULSE Compact 1 MHz**. This cable presents an alligator pin adaptor which is connected to the black banana pin in the electrostimulation cable in the **NEURODYN** line. The dispersive banana pin (red) of electrostimulation is connected to a dispersive electrode which is applied to the patient to close the electrical circuit. When the electric current output is generated by the stimulator, the current flows through the aluminum face of the transducer by means of this connection. (figure 9).

## INSTRUCTIONS FOR COMBINED THERAPY

**A** **B**

**Figure 8. A**, slot for combined therapy of **SONOPULSE Compact 1 MHz**; **B**, connector cable for combined therapy.

Reread all the precautions for neuromuscular electrical stimulation and the contra indications in the instructions of use of the electrostimulation equipment of the **NEURODYN** line before proceeding to the combined therapy.

The **SONOPULSE Compact 1 MHz** timer will control the time of ultrasound therapy, however, the same therapy time must be adjusted in the electrostimulator for the combined therapy. Press the **START** key in **SONOPULSE Compact 1 MHz** and in the electrostimulator to initiate the treatment. The intensity of electrostimulation is adjusted in the electrostimulator, whereas the intensity of ultrasound is adjusted in the **SONOPULSE Compact 1 MHz**. At the end of the programmed time, the emissions of ultrasound and electrical stimulation are interrupted and a sound beep will be emitted at the end of the treatment. Press the **STOP** key to stop the sound beep. The equipment may now be turned off, or perform the same program or record a new program.

## APPLICATION TECNIQUE FOR COMBINED THERAPY

Position of the ultrasound transducer and the electrostimulation electrode for combined therapy (Figure 10).

**Figure 9.** Application technique for combined therapy.

## USING THE MENU BUTTON
## SELECTION OF LANGUAGE

The **PROG/MENU** key is used to select the language. Press the **PROG/MENU** key until you hear three sound beeps. Select the desired language: "Portuguese", "Spanish" or "English". Press the **PROG/MENU** key again to define the chosen language. (figure 8).

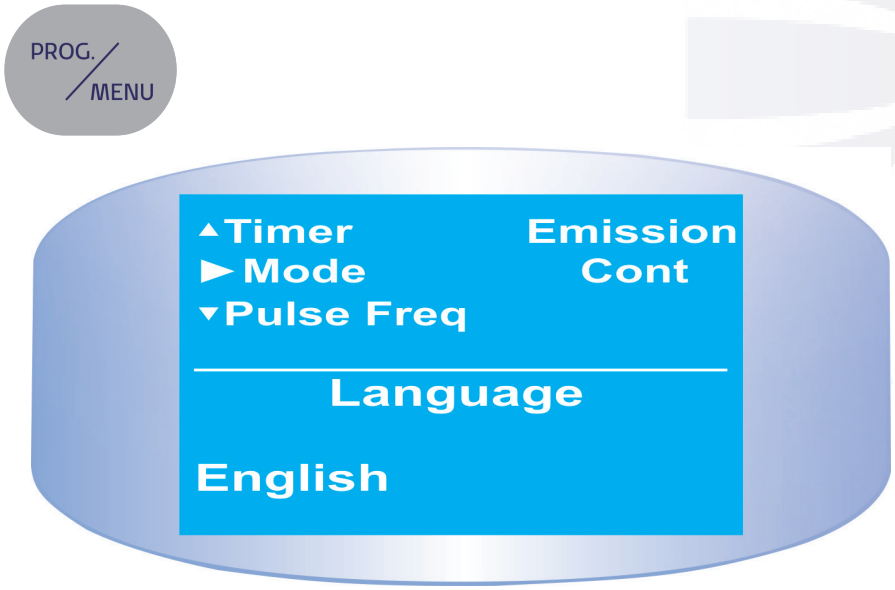



**Figure 10.** Message of selection of language.

## USING THE PROG BUTTON
## SELECTION OF PROGRAMMED PROTOCOLS

Turn the equipment on as described above. Press briefly the **PROG** key and press **SET** key to select the **PROGRAMMED** protocols. Next, the information of the first treatment protocol of the equipment will appear on the display. Use the **SET** key to select another protocol. See protocols details in section **CLINICAL RESOURCES LIBRARY.**

If the first treatment protocol is the chosen protocol, press the **PROG** key once more. The display will show the parameters for the selected protocol including the ultrasound intensity. Next, select the therapy time using the **SET** key and just press the **START** key.
Proceed on the same way to select any of the available protocols. Just follow the steps described above.

## PROGRAMMING PARTICULAR PROTOCOLS

To program new protocols, press briefly the **PROG** key and press **SET** key to select the **USER** protocols. Using the **SET** key choose one of the 20 **USER** protocols available. Adjust the parameters according to the therapeutic needs and press **START**. The last parameters defined will be recorded in the memory of the device. To access the protocols saved by the user, just select the **PROG** key and use the **SET** key to choose the number of the desired protocol.

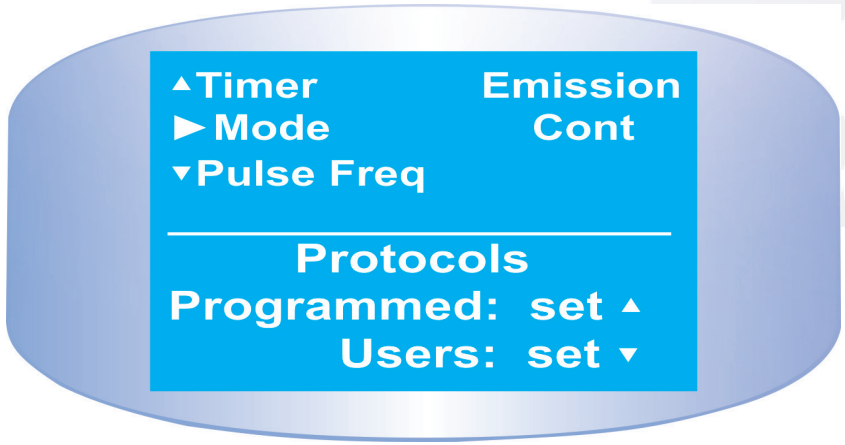



**Figure 11.** Programmed and User protocols display.

| **Protocol 1 - 1 MHz** | |
|---|---|
| **Femoral Biceps Injury Acute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 2 W/cm² |
| Treatment time | 1-30 min* |

| **Protocol 2 - 1 MHz** | |
|---|---|
| **Rectus Femoris Injury Acute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 1.5 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| **Protocol 3 - 1 MHz** | |
|---|---|
| **Anterior Tibial Injury-Acute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 0.8 W/cm² |
| Treatment time | 1-30 min* |

| **Protocol 4 - 1 MHz** | |
|---|---|
| **Deltoid Muscle Injury-Acute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 0.8 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| Protocol 5 - 1 MHz | |
|---|---|
| **Rhomboid Injury<br>Acute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 1.5 W/cm² |
| Treatment time | 1-30 min* |

| Protocol 6 - 1 MHz | |
|---|---|
| **Femoral Biceps Injury<br>Subacute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 50 % |
| Pulse frequency | 100 Hz |
| Intensity | 2 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

*The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| **Protocol 7 - 1 MHz** | |
|---|---|
| **Rectus Femoris Injury Subacute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 50 % |
| Pulse frequency | 100 Hz |
| Intensity | 1.5 W/cm² |
| Treatment time | 1-30 min* |

| **Protocol 8 - 1 MHz** | |
|---|---|
| **Anterior Tibial Injury-Subacute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 50 % |
| Pulse frequency | 100 Hz |
| Intensity | 0.8 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| **Protocol 9 - 1 MHz** | |
|---|---|
| **Deltoid Muscle Injury-Subacute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 50 % |
| Pulse frequency | 100 Hz |
| Intensity | 0.8 W/cm² |
| Treatment time | 1-30 min* |

| **Protocol 10 - 1 MHz** | |
|---|---|
| **Rhomboid Injury Subacute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 50 % |
| Pulse frequency | 100 Hz |
| Intensity | 1.5 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| Protocol 11 - 1 MHz | |
|---|---|
| **Reduction of Muscle Spasm - Deltoid** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 0.8 W/cm² |
| Treatment time | 1-30 min* |

| Protocol 12 - 1 MHz | |
|---|---|
| **Reduction of Muscle Spasm - Cervical Paraspinal** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 0.8 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| **Protocol 13 - 1 MHz** | |
|---|---|
| **Reduction of Muscle Spasm - Thoracic Paraspinal** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 1.6 W/cm² |
| Treatment time | 1-30 min* |

| **Protocol 14 - 1 MHz** | |
|---|---|
| **Reduction of Muscle Spasm - Lumbar Paraspinal** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 2 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| Protocol 15 - 1 MHz | |
|---|---|
| **Reduction of Muscle Spasm - Rhomboid** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 1 W/cm² |
| Treatment time | 1-30 min* |

| Protocol 16 - 1 MHz | |
|---|---|
| **Reduction of Muscle Spasm – Biceps or Triceps Brachii** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 0.8 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| Protocol 17 - 1 MHz | |
|---|---|
| **Reduction of Muscle Spasm - Gastrocnemius** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 1.6 W/cm² |
| Treatment time | 1-30 min* |

| Protocol 18 - 1 MHz | |
|---|---|
| **Reduction of Muscle Spasm – Biceps Femoris** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 2 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| Protocol 19 - 1 MHz | |
|---|---|
| **Reduction of Muscle Spasm – Rectus Femoris** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 1.5 W/cm² |
| Treatment time | 1-30 min* |

| Protocol 20 - 1 MHz | |
|---|---|
| **Trochanteric Bursitis Acute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 1 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

*The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| **Protocol 21 - 1 MHz** | |
|---|---|
| **Trochanteric Bursitis Chronic Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 1 W/cm² |
| Treatment time | 1-30 min* |

| **Protocol 22 - 1 MHz** | |
|---|---|
| **Gluteus Medius Tendinopathy Acute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 1 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| Protocol 23 - 1 MHz | |
|---|---|
| **Supraspinal Tendinopathy Acute Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 1.8 W/cm² |
| Treatment time | 1-30 min* |

| Protocol 24 - 1 MHz | |
|---|---|
| **Gluteus Medius Tendinopathy Chronic Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 1 W/cm² |
| Treatment time | 1-30 min* |

IBRAMED

***The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

| **Protocol 25 - 1 MHz** | |
|---|---|
| **Supraspinal Tendinopathy Chronic Phase** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Continuous |
| Intensity | 1.8 W/cm² |
| Treatment time | 1-30 min* |

| **Protocol 26 - 1 MHz** | |
|---|---|
| **Sonophoresis (Rehabilitation)** | **Parameters values** |
| Frequency | 1 MHz |
| Mode | Pulsed |
| Duty cycle | 20 % |
| Pulse frequency | 100 Hz |
| Intensity | 1 W/cm² |
| Treatment time | 1-30 min* |

| **Prog: 1 to 20 - User Protocols** |
|---|

*****The treatment time depends of the size of the treatment area and the ERA (Effective Radiating Area) of the transducer. The operator must calculate the treatment time according to the size value of the treatment area divided by the value of the ERA of the transducer selected for the treatment.

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# ACCESSORIES WHICH ACCOMPANY SONOPULSE COMPACT 1 MHZ

**SONOPULSE Compact 1 MHz** contains accessories conceived to satisfy the demands of electromagnetic compatibility – accessories coded **03017006** and **02049048**.

| CODE | QTT | DESCRIPTION OF ITEM |
|---|---|---|
| **03017006** | 01 | PP FEMALE CABLE IEC-2X0,75X1500MM |
| **03040004** | 01 | DIGITAL OPERATIONS MANUAL IBRAMED 100511 |
| **02049048** | 01 | SILICONE HEAD KIT WITH NTC |
| **03026009** | 01 | PROTECTION FUSE CARD |
| **03019012** | 01 | 20AG FUSE OF 5A |
| **03026003** | 01 | BAG SAFIRA LINE |
| **03044001** | 01 | TUBE OF GEL (CAP.100 GRAMS)<br>REGISTER ANVISA N° 80122200001 |

**WARNING**

The use of accessories, ultrasound transducer and cables and electrodes different from the ones for which the device was designed may significantly degrade the performance of emissions and immunity. Therefore, DO NOT USE accessories, ultrasound transducer, cables and electrodes of **SONOPULSE Compact 1 MHz** in other equipment or electromedical systems.

The accessories, electrodes and cables described in these instructions of use and manufactured by IBRAMED are for the sole use with **SONOPULSE Compact 1 MHz** equipment.

## REPLACEMENT ACCESSORIES

The replacement accessories are designed for use with **SONOPULSE Compact 1 MHz**. As you order them, provide the respective codes, description and quantity desired.
The use of accessories, cables and transducer Other than the ones destined for this specific equipment may degrade significantly the performance and immunity. Do not use accessories, cables and transducer of **SONOPULSE Compact 1 MHz** in other equipment or electromedical systems.

What may initially appear to be a problem not always is really a defect. Therefore, before turning to technical assistance, check the items described in the table below.

| PROBLEMAS | SOLUÇÃO |
|---|---|
| The equipment does not turn on 1 | Is the power cable properly connected?<br>If it is not, connect it. Also check the power outlet on the wall. |
| The equipment does not turn on 2 | Have you checked the protection fuse? Check if they are **properly connected**. Check also if the value is in accordance with the indicated in the operation instructions. |
| The equipment is on but does not perform the function. | Have you followed the recommendations and instructions in the operation manual correctly? Check and go over the steps indicated in the item about **controls**, **indicators** and **connections**; and in the item **operation instructions**. |



## MAINTENANCE

For the safe use of the equipment, we recommended to have it inspected and undergo preventive maintenance at IBRAMED or an authorized technical center **every 12 months**.

IBRAMED manufacturer only assumes liability for the technical features and equipment safety provided the unit is used according to the instructions for use contained in the manual, when maintenance, repairs and modifications are undertaken solely by the factory or authorized agents, and in the event of a breakdown when the components that can cause a security risk to the appliance are replaced by original spare parts. If requested, IBRAMED will provide technical documentation (circuit diagrams, lists of parts and components etc.) necessary for the repair of any equipment.

We assume no responsibility for repairs without prior explicit written permission from IBRAMED.

## WARRANTY

IBRAMED, Indústria Brasileira de Equipamentos Médicos EIRELI, here identified to the consumer through the following address and telephone number: Av. Dr. Carlos Burgos, 2800, Jd Itália, Amparo/SP; Tel.: 55 19 3817 9633 provides product-warranty for eighteen (18) months insofar as the conditions set for warranty terms are followed by the user as mentioned below.

## WARRANTY TERMS

1) IBRAMED warrants that this product is free of manufacturing defects for eighteen (18) continuous months provided the set terms presented in these instructions for use are followed.

2) The warranty period takes effect from the date of purchase and applies to the original purchaser only, even in the event of a product being transferred to a third party. The warranty covers the replacement of component parts and labor required to repair defects whenever the presence of such manufacturing defects can be determined.

3) Customer Service during the warranty period will be provided exclusively at IBRAMED sale points by IBRAMED itself or another agent designated by the manufacturer.

4) The warranty does not cover damage caused to the product resulting from:

a) Failure to follow the specifications and recommendations detailed in these instructions for use during installation or use of the product.

b) Accidents or acts of God, connections to electrical system with inappropriate voltage and/or subjected to excessive fluctuation or overcharge.

c) Misuse, lack of reasonable care, product alterations, modifications or repairs undertaken by individuals or entities not authorized by IBRAMED.

d) Removal or adulteration of the equipment serial number.

e) Damage during Transport.

5) The legal warranty does not cover: expenses incurred during product installation or transport to the plant or sale point, labor, materials, parts and adjustments necessary to the readiness of the premises in view of the installation of the device, such as but not limited to electric net, masonry, hydraulic network, grounding system, as well as their requirements.

6) The warranty does not cover parts subjected to natural wear, such as but not limited to control buttons, control keys, handles and moving parts, cables, connectors, device cabinets.

7) The selling points are neither authorized to alter the conditions mentioned in this document nor to take any commitment on behalf of IBRAMED.

## TECHNICAL ASSISTANCE

If you have any doubts or problems related to the operation of your equipment please contact our technical department. Call: **19 3817 9633.**

**WARNING**

Do not alter this equipment. Any unauthorized modification can affect the safety of this equipment.
**Never make unauthorized repairs.**

IBRAMED Equipment goes beyond technology. It also provides knowledge! Science constitutes our differential value and we effectively take advantage of its benefits in order to ensure patient safety and thereby maximize results.

IBRAMED develops products with scientific support of the most recent medical studies published in major scientific journals in the areas of biological, health and exact.

Access to the knowledge database is guaranteed by CEFAI (IBRAMED Center for Education and Advanced Training) whose goal is to provide technical and scientific support as well as current literature on therapies and their applicability while our treatment choices are always thoroughly selected according to the best and latest clinical criteria. CEFAI takes into account the personal and professional development of all its partners and customers.

CEFAI invites both students and professionals in the fields of Physical Rehabilitation, Esthetics, Physiotherapy, Dermatology and Esthetic Medicine to take part in free courses, workshops, and the best Postgraduate *Lato Sensu* courses in the areas of physical rehabilitation and esthetics.

Special attention is also given to those interested in visiting our structure. Whatever your professional development needs, we'll be right by your side to provide you with unconditional support.

We are happy to assist you!

Contact – **cefai@conexaocefai.com.br**
www.conexaocefai.com.br
+55 19 3808. 2348

Thanks,

**IBRAMED – A matter of respect!**

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CENTRO DE ESTUDOS E FORMAÇÃO AVANÇADA IBRAMED

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QUESTÃO DE RESPEITO

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Indústria Brasileira de Equipamentos Médicos EIRELI.
Av. Dr. Carlos Burgos, 2800 - Jd. Itália
13901-080 - Amparo - SP - Brasil
19 3817 9633
www.ibramed.com.br
ibramed@ibramed.com.br